

REMARKS

Claims 1-37 are pending in the application. Claims 1-23, 26-34, and 36-37 are withdrawn pursuant to a restriction requirement. Favorable reconsideration in light of the amendments, the new claims, and the remarks which follow is respectfully requested.

I. The Amendments

Claims 24 and 35 are amended to disclaim the cited art by reciting that the primer pair has a property wherein the primer pair does detect or prime ruminant-derived DNA. Claim 24 is amended to disclaim the cited art by reciting the transitional phrase "consisting of" to indicate that the claimed primes have the same identity as the Sequences disclosed in the Sequence Listing. The amendments are fully supported throughout the Specification, for example, pages 10-11 and Figures 6-7 and accompanying text.

II. Rejection of Claims 24, 25, and 35 Under 35 U.S.C. § 103(a)

Claims 24, 25, and 35 stand rejected under 35 U.S.C. § 103(a) over Saulle et al (*Animal Sci.* 77, 3398-99 (1999) in view of Lowe et al (*Nuc. Acid Res.*, 18, 1757-61 (1990)). Applicant's representative believes that sufficient evidence has been presented to rebut the obviousness rejection

The Applicant's best understanding of the Examiner's rejection is as follows. The Examiner appears to state that the claimed primer sequences have a degree of complementarity with the gene sequences disclosed in Saulle et al. The Examiner states that one skilled in the art would be motivated to make the claimed primer sequences basis for the purpose of amplifying the genes of Saulle et al by PCR for the uses that PCR is ordinarily employed in the art.

Applicant's representative does not concede as a matter of record that the Examiner has established a sufficient *prima facie* argument for obviousness. However, the comments presented are not directed toward or against the arguments stated by the Examiner based upon Lowe et al and Saulle et al. The courts have long-held that even a *prima facie* case of obviousness stated by an

Examiner can be rebutted by an Applicant through certain evidentiary showings by the Applicant. That is, the Examiner's theoretical showing of a *prima facie* argument for obviousness is not conclusive as to ultimate patentability and merely shifts the burden of proof to the Applicant to produce evidence rebutting the rejection. It is respectfully submitted that the declaration under 37 C.F.R. § 1.132 submitted with the reply to the Office Action dated Sept. 30, 2009, provides sufficient evidence to rebut any *prima facie* case of obviousness stated by the Examiner.

Under the *Papesch* doctrine [*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)] evidence of unobvious or unexpected advantageous properties may rebut a *prima facie* case of obviousness based on structural similarities. . . Such evidence may include data showing that a compound is unexpectedly superior in a property it shares with prior art compounds. . . . Evidence that a compound is unexpectedly superior in one of a spectrum of common properties . . . can be enough to rebut a *prima facie* case of obviousness.

In re Chupp, 816 F.2d 643, 646, 2 USPQ2d 1437 (Fed. Cir. 1987) (emphasis added).

The *Chupp* court held that an obviousness rejection to a claimed species of herbicide, structural similar to a prior art genus of herbicides, was rebutted by a showing that the claimed species of herbicide were unexpectedly superior in effectiveness against two types of weeds (quackgrass and yellow nutsedge). *Id.* at 647. The prior art genus of herbicides cited in the obviousness rejection in *Chupp* was known to have herbicide properties; however, a showing that the claimed, undisclosed species had an "unexpectedly superior" herbicide property was "sufficient to rebut the *prima facie* case of obviousness." *Id.*

Here, the Examiner appears to assert that the genus of primers produced by the application of Lowe et al to the genes of Saulle et al is expected to

produce a genus of primers having the property and ability to “amplify and increase the primer specificity and to amplify and detect a ruminant-specific DNA.” Final Office Action, dated Sept. 30, 2009, page 3.

However, one having skill in the art would also expect the genus of primers generated by the combination of Lowe et al and Saulle et al to be able to cross-prime and amplify highly analogous DNA sequences that may not necessarily be derived from ruminants. The mitochondrial *ATPase* genes are highly conserved between eukaryotic organisms since such genes are necessary for cellular respiration. The Rule 1.132 declaration submitted with the reply to the Office Action dated Sept. 30, 2009, shows that such cross-priming occurs with other primer sequence tested by the Applicants that are also complementary with the genes of Saulle et al.

The Declaration in Appendices 2 and 3, presents eight primer pairs labeled Cases 1-8 that are not the claimed primer pair. In Appendix 3, the following properties are observed for cases 1-8:

Case 1: Detects ruminant species but with uneven product size between species.

Case 2: Detects both ruminant goat and non-ruminants pig, horse and chicken.

Case 3: Detects all species presented both ruminant and non-ruminant.

Case 4: Detects no ruminants and detects non-ruminants chicken and horse.

Case 5: Detects all species presented both ruminant and non-ruminant.

Case 6: Detects ruminant goat and non-ruminants pig and horse.

Case 7: Detects ruminant sheep and non-ruminants pig, chicken and horse

Case 8: Detects ruminant sheep and non-ruminant pig.

Cases 1-8 are representative of the properties one skilled in the art would expect of primers complementary to the gene sequences of Saulle et al.

Specifically, due to the high degree of homology of the *ATPase* genes across species, a degree of cross-reactivity and cross-priming is expected. Appendix 3 of the Declaration shows that such is observed.

As such, the claimed primer pair has an “unexpectedly superior” property “sufficient to rebut the *prima facie* case of obviousness” as sanctioned by the Federal Circuit as articulated in *Chupp*. The “unexpectedly superior” property of the recited primer pairs is non-cross reactivity with non-ruminant species and to produce a product of a consistent size.

In regards to the herbicides of *Chupp*, the specific chemical species (i.e. herbicides) found to be patentable by the court had superior herbicide properties against quackgrass and yellow nutsedge. 816 F.2d at 647. Undoubtedly, the superiority against quackgrass and yellow nutsedge is an intrinsic property of the specific herbicide species at issue in *Chupp*. However, the claimed herbicides in *Chupp* were found to be patentable nevertheless since one skilled in the art would not expect those particular compounds to have such intrinsic properties. “[E]vidence of unobvious or unexpected advantageous properties may rebut a *prima facie* case of obviousness.” *Chupp*, F.2d at 646. Here, the properties of the claimed primers of non-cross reactivity with non-ruminant species and consistent size of PCR products between species are as equally unexpended as the enhanced pesticide properties of *Chupp*, as demonstrated in the Declaration.

The ability of an Applicant to rebut even a valid *prima facie* obviousness rejection is well-recognized by the Federal Circuit. Further, the MPEP states the continued validity of the so-called *Papesch* doctrine [*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)] in § 2144.09 (VII).

The “*Papesch* doctrine” is currently controlling law in the Federal Circuit and has been cited favorably in recent post *KSR Int’l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007), opinions and cited as controlling law in MPEP §§ 2141-2144. See, e.g., *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1086 (Fed. Cir. 2008) (“[T]he structure of the compound and its properties are inseparable considers in the obviousness determination.”) (citing *In re Papesch*, 315 F.2d at 391); *In re Sullivan*, 498 F.3d 1345, 1353 (Fed. Cir. 2007) (“The issue here is not

whether a claim recites a new use, but whether the subject matter of the claim possesses an unexpected use. That unexpected property is relevant, and thus the declarations describing it should have been considered by the Board.”) (citing *In re Papesch*, 315 F.2d at 391, for stating “from the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing”); see also MPEP § 2144.09(VII).

The recent decision of *In re Sullivan*, 498 F.3d 1354, is particularly relevant to the instant application. There, specific claimed Fab fragments (not claimed as a method) having antivenom properties were rejected by the Board for obviousness without the Board considering three declarations of the Applicant. The Federal Circuit vacated the Board’s decision by stating “[w]hether the composition would have been obvious cannot be determined without considering evidence attempting to rebut the prima facie case,” since “[t]here was no showing of unpatentability under § 102.” *Id.* at 1351-52.

In re Sullivan is a case from 2007 stating the necessity of a direct consideration of “evidence attempting to rebut the prima facie case” by the Examiner and/or Board. It is noted that the Declaration was submitted after the prior appeal in this case. It is respectfully submitted that the Examiner has not stated why the evidence submitted in the above-discussed Declaration is not sufficient for the purpose of rebutting the obviousness rejection. The Examiner is respectfully asked to state if and why the Evidence presented in the above-discussed Declaration lacks sufficiency to rebut a *prima facie* case of obviousness of the claimed primer pairs. Whether the claimed primers “would have been obvious [to a person skilled in the art] cannot be determined without considering evidence attempting to rebut the prima facie case.” *Sullivan*, 498 F.3d at 1351-52. A restatement of an obviousness rejection from the teachings of Lowe et al and Saulle et al is not relevant to the issue of sufficiency of the rebuttal evidence presented in the Declaration and argued above.

Since Applicant’s representative believes that sufficient evidence has been presented to rebut the obviousness rejection, it is respectfully requested

that the rejection of claims 24, 25, and 35 under 35 U.S.C. § 103(a) be withdrawn.

Nevertheless, Applicant's representative provides these additional comments explaining why a *prima facie* case of obviousness has not been established. The Examiner contends that some of the primer sequences recited in claims are described in Saulle et al. Thus, the Examiner also necessarily contends that some of the primer sequences recited in claims **are not** described in Saulle et al. In claims 24 and 35, the primer sequence of SEQ ID NO: 3 contains mixed bases at 3 positions. This means that the sequence of SEQ ID NO: 3 actually consists of 2^3 or 8 different sequences. As a result, in a PCR reaction solution, there is a mixture of 8 primers in a specific ratio (i.e., each equivalent amount) each having a specific sequence regarding the primer sequence of SEQ ID NO: 3. Applicant's representative notes that the specific mixture of 8 primers enables the ruminant specific PCR. This situation is also applicable to the primer sequence of SEQ ID NO: 4. Consequently, those skilled in the art would not have easily arrived at such a combination of sequences. For this additional reason, it is respectfully requested that the rejection of claims 24, 25, and 35 under 35 U.S.C. § 103(a) be withdrawn.

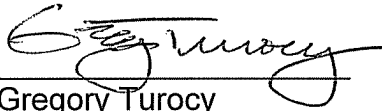
III. Petition for Extension of Time

A request for a three-month extension of time is hereby made. Payment is made *via* the EFS filing system.

In the event any fees are due in connection with this document, the Commissioner is authorized to charge those fees to Deposit Account No. 50-1063.

Should the Examiner believe a telephone interview would be helpful to expedite favorable prosecution, the Examiner is invited to contact applicant's undersigned representative at the telephone number listed below.

Respectfully submitted,
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